IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Malyarov et al.	Docket No.:	2006P26174 US
Application No.:	10/813,575	Examiner:	WRIGHT
Filed:	3/31/2004	Art Unit:	1797
Customer No.:	28624	Confirmation No.:	4329

For: Rotary Luminometer

Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Sir:

This is an appeal from the final rejection mailed September 10, 2008. A Notice of Appeal was timely filed on February 24, 2009.

REAL PARTY IN INTEREST:

The real party in interest is Siemens Healthcare Diagnostics Inc. of Tarrytown, NY.

RELATED APPEALS AND INTERFERENCES:

To the best of the undersigned's knowledge, there are no related interferences or judicial proceedings.

STATUS OF CLAIMS:

Claims 1 – 18 are pending in the application. Claims 1 – 17 are rejected. Claim 18 has been withdrawn from further consideration. Claims 1 – 17 are being appealed. No claims are allowed or confirmed. No claims are objected to. No claims are canceled.

STATUS OF AMENDMENT:

No amendment to the claims or to the specification was filed subsequent to the final rejection mailed September 10, 2008.

SUMMARY OF CLAIMED SUBJECT MATTER:

The present invention relates to reagent analyzing equipment, and in particular to a read station that is capable of rotating a transferred analyte sample vessel from an entry position to a read position, where radiant energy emanating from the read station is detected by a detector, independently of motion of a plurality of vessels through a defined path as transported by a transport device.

Independent claim 1 relates to an analyte detection station for an automated immunoassay analyzer, comprising:

a read station rotatable between an entry position and a read position[1];

a detector coupled to said read station at said read position for detecting radiant

[1] Page 8, line 27 – page 9, line 2 and page 9, lines 12 – 14 of the specification as filed.

energy or color emanating from said read station;[2]

a wash station that performs a wash operation;[3]

a transport device that receives vessels from said wash station[4] and for transporting a plurality of vessels from said wash station through a defined path,[5] each of said vessels containing at least one bound analyte and at least one compound for emitting radiant energy or color,[6] and for transferring one of said plurality of vessels from said defined path into said read station at said entry position;[7]

wherein said read station is capable of rotating a transferred vessel from said entry position to said read position independently of motion of said plurality of vessels through said defined path.[8]

Claim 5 relates to the analyte detection station for an automated immunoassay analyzer as recited in claim 1, wherein said read station includes a shield for shielding said transferred vessel from external radiant energy when it is transferred to said read position when said detector is detecting said radiant energy.[9]

Claim 6 relates to the analyte detection station for an automated immunoassay analyzer as recited in claim 5, wherein said read station biases the vessel in said read station a set distance from the detector when in the read position.[10]

All other claims are dependent on claim 1 and summary of their subject matter is omitted as unnecessary.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL:

At issue in this appeal is whether the Office action erred in rejecting claims 1 – 17 under 35 U.S.C §102(b) as being anticipated by US 5,885,529 to Babson et al. (hereinafter, "Babson").

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[2] Page 8, line 31 – page 9, line 2 and page 4, lines 10 – 13 of the specification as filed.
[3] Page 7, lines 3 – 5 of the specification as filed.
[4] Page 7, lines 3 – 6 of the specification as filed.
[5] Page 7, line 7 – 8 and figure 2 of the specification as filed.
[6] Page 2, line 28 – page 3, line 2 of the specification as filed.
[7] Page 7, lines 17 – 18 and figure 2 of the specification as filed.
[8] Page 7, line 25 – page 8, line 19 of the specification as filed.
[9] Page 9, lines 15 – 22 of the specification as filed.
[10] Page 9, lines 22 – 27 of the specification as filed.

ARGUMENT:

The rejection of claims 1 – 17 under 35 U.S.C §102(b) over Babson is improper and should be reversed. Anticipation can only be established by a single prior art reference which discloses "[t]he identical invention ... in as complete detail as is contained in the patent claim."[11] Here, Babson clearly fails to disclose every element of the claimed invention, as will be demonstrated herein. As explained in the specification, automated immunoassay analyzers as disclosed by Babson have traditionally performed testing of samples in a serial manner. That is, a sample is presented to the analyzer and it progresses step by step through the various processes until completion. While this first sample is progressing through the analyzer, all other samples follow. That is, there is a single path through currently available analyzers. Once the sample reaches the luminometer subsystem, it is then read using a detection mechanism while on the transportation element. This means the readings must be performed in a serial fashion on a first come first serve basis.

As disclosed, luminometer chain 215a picks up vessels from wash station 214 and transports them to reading station 216, where photometric reading of the reagent in the vessels is read by photomultiplier tube 216a, one at a time in a serial fashion, after which the vessel and its contents are moved by the chain 215a to waste.

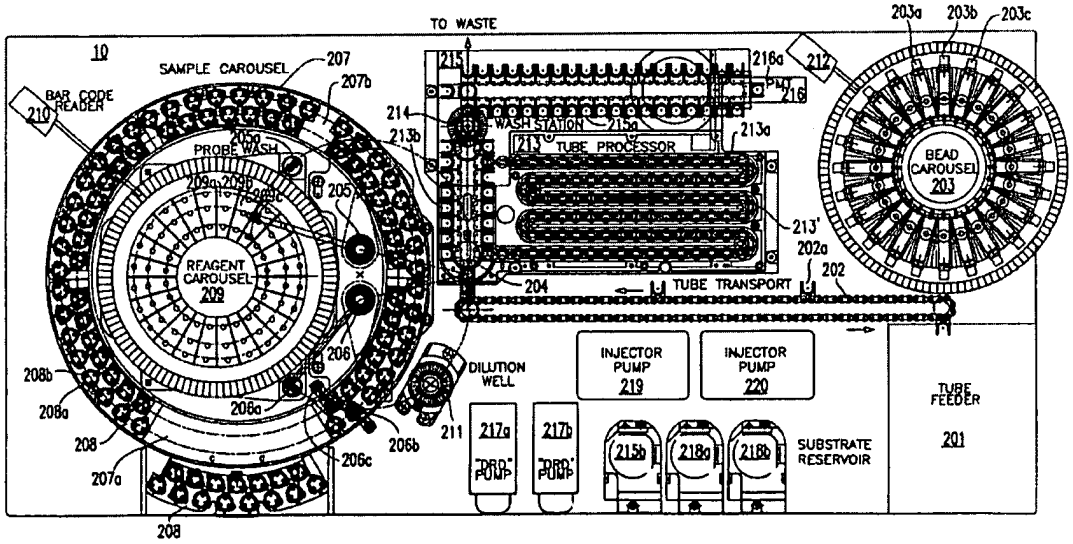

FIG.2A

[11] *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989).

Contrary to the position taken in the Office action, Babson fails to disclose a read station rotatable between an entry position and a read position. In fact, the Office action itself recognizes that the only movable mechanism is the luminometer chain 215a. The read station 216 is stationary and does not rotate at all. The Office action apparently attempts to interpret the chain 215a as being the read station. The chain 215a clearly is not the read station as disclosed by Babson. Babson distinguishes between the chain 215a and the read station 216. Thus, interpreting the chain 215a as the read station according to the Office action thus not only is inconsistent with the present specification, which distinguishes between read station 2 and transport belt 3, but is also inconsistent with the Babson disclosure itself, and therefore is outside the broadest reasonable standard of claim interpretation that must be used in examination. No one of any skill in the art would ever interpret the transport chain as a "read station."

However, such claim interpretation also is improper because it fails to consider the language of claim 1 as a whole. That is, claim 1 not only requires a rotatable read station, but also requires a transport device for transferring one of the plurality of vessels into the read station at the entry position thereof. The chain 213b does not transport vessels into the read station 216 (and neither does it transport vessels "into" the chain 215a), but instead transports vessels from the end back to the beginning of serpentine channel 213' (see col. 8, ll. 4-6). Babson further discloses that if a vessel needs to be moved to wash station 214, it is shuttled out of tube processor 213 and picked up by a separate "circular chain" to be moved to wash station 214 (see col. 8, ll. 6-10). Thus, chain 213b does not transfer vessels into a read station as required by the claims.

The Advisory Action of December 16, 2008 asserts

> There is no structure claimed that distinguishes the 'read station' in claim 1 from the oval luminometer chain 215a of Babson, which rotates between an entry position (at wash station 214) and a read position at a detector (photomultiplier tube (PMT)); (col. 8, line 31; Figs. 2a, 2b of Babson).

In response, it is pointed out that claim language is to be read not in a vacuum, but in light of the specification to be consistent with the specification. Claim 1 requires "a read station rotatable between an entry position and a read position." The chain 215a of

Babson is a transport mechanism and not a "read station." The statement in the Advisory action further ignores the claim language as a whole in favor of improper consideration of individual claim limitations in isolation and disconnected from the other claim limitations of which they form an integral whole.

To wit, claim 1 also requires "a transport device that receives vessels from [a] wash station and for transporting a plurality of vessels from said wash station through a defined path ... and for transferring one of said plurality of vessels from said defined path into said read station at said entry position." In setting out the structural interrelationships between the elements, claim 1 indicates the entry position of the read station receives a vessel from a defined path through which a transport device transports a plurality of vessels from the wash station. The presence of the defined path between the entry position and the wash station indicates the read station is not "at the wash station" as alleged in the Advisory action.

The Advisory Action also states,

> The analyzer of Babson includes a transport device 213b (side chain) for transporting a plurality of vessels 27 through a defined path. The transport device 213b receives the vessels from the wash station and transports the reaction tubes to reaction pipeting station 204 along a path defined by the side chain 213b. After reagent addition, the transport device (chain 213b) transfers the reaction from the path (chain 213b) to the wash station where the step of incubation and wash are repeated (see col. 8, lines 21 – 29) and into the read station (i.e., 215a) at the entry position. In other words, Babson teaches transport from a wash station to a defined path and from the defined path back into the wash station and into a read station. The open language of the claims do not preclude the transport device transferring the plurality of vessels from the defined path of the transport device and into the read station via the wash station 214.

Appellants respectfully disagree. "'Comprising' is not a weasel word with which to abrogate claim limitations." *Spectrum International, Inc. v. Sterilite Corporation*, 164 F.3d 1372, 1380 (Fed.Cir. 1998). The claims require a transport device that receives vessels from said wash station and for transporting a plurality of vessels from said wash station through a defined path, and for transferring one of said plurality of vessels from said

defined path into said read station at said entry position. The claims do not encompass transporting vessels from a defined path of a transport device through a wash station into a read station, but to the contrary, require transport from a wash station to a defined path, and from that defined path into a read station. The final rejection has simply ignored these claim requirements in alleging that Babson anticipates the claimed invention. When the actual language of claim 1 is considered, it is clear that Babson does not disclose the claimed invention but to the contrary is representative of the acknowledged prior art, of which the present invention provides a substantial and significant real world improvement.

For at least these reasons, appellants respectfully submit claims 1 – 17 are not anticipated by Babson and the rejection should be reversed.

Claim 5 further distinguishes over Babson. Claim 5 requires that the read station include a radiation shield for shielding the vessel from radiant energy when it is transferred to the read position when the detector is detecting radiant energy. The final rejection alleges that the un-illustrated "shutter" mentioned in Babson meets this limitation. This is erroneous, because Babson does not disclose that the chain 215a, which the Examiner interprets as the "read station," includes a shutter. As such, even if the erroneous and improper interpretation of the "read station" limitation as reading on a transport chain is adopted, the rejection of claim 5 is in error and cannot be sustained since it is inconsistent not only with the specification and with Babson, but also is internally inconsistent with the rejection itself.

Claim 6 further distinguishes over Babson. Babson does not teach or suggest biasing a test vessel in the read station a set distance from the detector when in the read position. On page 5, the final Office action of September 10, 2008 asserted

> the Examiner considers the read station oval luminometer chain 215a as 'biasing' the test vessel a set distance from the detector when in the read position before the PMT.

In order for claim 6 to have a scope that is not identical to claim 1, claim 6 must be read to require the read station to impart a bias to a test vessel when in the read position that is different from any bias otherwise imparted. Babson does not describe chain 215a as imparting a unique bias when it has transported a vessel to the stationary read station 216. Thus, this ground of rejection is also improper and should be reversed.

Conclusion

In view of the foregoing, claims 1 – 17 are submitted to define a novel and unobvious analyte detection station that is not taught or disclosed by the prior art. The present application is in condition for allowance, and the Honorable Board is requested to reverse all grounds of rejection and to direct the passage of this application to issue.

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CLAIMS APPENDIX:

1. (Previously presented) An analyte detection station for an automated immunoassay analyzer, comprising:

a read station rotatable between an entry position and a read position;

a detector coupled to said read station at said read position for detecting radiant energy or color emanating from said read station;

a wash station that performs a wash operation;

a transport device that receives vessels from said wash station and for transporting a plurality of vessels from said wash station through a defined path, each of said vessels containing at least one bound analyte and at least one compound for emitting radiant energy or color, and for transferring one of said plurality of vessels from said defined path into said read station at said entry position;

wherein said read station is capable of rotating a transferred vessel from said entry position to said read position independently of motion of said plurality of vessels through said defined path.

2. (Original) The analyte detection station for an automated immunoassay analyzer as recited in claim 1, wherein said detector detects chemiluminescence.

3. (Original) The analyte detection station for an automated immunoassay analyzer as recited in claim 1, wherein said detector detects fluorescence.

4. (Original) The analyte detection station for an automated immunoassay analyzer as recited in claim 1, wherein said detector detects phosphorescence.

5. (Previously presented) The analyte detection station for an automated

immunoassay analyzer as recited in claim 1, wherein said read station includes a shield for shielding said transferred vessel from external radiant energy when it is transferred to said read position when said detector is detecting said radiant energy.

6. (Previously presented) The analyte detection station for an automated immunoassay analyzer as recited in claim 5, wherein said read station biases the vessel in said read station a set distance from the detector when in the read position.

7. (Previously presented) The analyte detection station for an automated immunoassay analyzer as recited in claim 5, wherein said read station operates by rotational movement.

8. (Previously presented) The analyte detection station for an automated immunoassay analyzer as recited in claim 5, wherein said read station further moves said transferred vessel to a disposal position for disposing of said vessel after it moves said vessel to said read position.

9. (Previously presented) The analyte detection station for an automated immunoassay analyzer as recited in claim 8, wherein said read station operates by rotational movement.

10. (Original) The analyte detection station for an automated immunoassay analyzer as recited in claim 1, wherein said transport device is a continuous carousel, chain or belt which includes a plurality of vessel receptacles for receiving each of said plurality of vessels.

11. (Previously presented) The analyte detection station for an automated immunoassay analyzer as recited in claim 10, wherein said continuous chain or belt can receive vessels in said vessel receptacles at a plurality of locations.

12. (Previously presented) The analyte detection station for an automated immunoassay analyzer as recited in claim 1, further comprising an attenuation means for attenuating light signals entering said detector from said read station.

13. (Previously presented) The analyte detection station for an automated immunoassay analyzer as recited in claim 12, wherein said attenuation means is located between said read station and said detector, wherein said attenuation means can be set at any one of at least two attenuation positions.

14. (Previously presented) The analyte detection station for an automated immunoassay analyzer as recited in claim 13, wherein said any one of at least two attenuation positions include: an unattenuated position where light from said vessel can be read directly by said detector, and an attenuated position where light from said vessel can be read by the detector through a neutral density filter.

15. (Previously presented) The analyte detection station for an automated immunoassay analyzer as recited in claim 12, wherein said attenuation means is located between said read station and said detector, wherein said attenuation means can be set at any one of at least three attenuation positions.

16. (Previously presented) The analyte detection station for an automated immunoassay analyzer as recited in claim 15, wherein said any one of at least three attenuation positions include: an unattenuated position where light from said vessel can be read directly by said detector, a dark position where no light from said vessel can be read by said detector, and an attenuated position where light from said vessel can be read by the detector through a neutral density filter.

17. (Previously presented) The analyte detection station for an automated immunoassay analyzer as recited in claim 1, further comprising means for measuring dark counts for determining ambient light levels within the detector.

18. (Withdrawn) In an analyte detection station for an automated immunoassay analyzer having a detector for detecting radiant energy or color emanating from a vessel containing at least one bound analyte and at least one compound for emitting radiant energy or color, the improvement comprising:

a transport device that receives vessels at a receiving position and transports a plurality of vessels through a defined recirculating path toward said detector; and

a read station located between said detector and said transport device, rotatable between an entry position adjacent to said transport device and a read position adjacent to said detector, said read station receiving a vessel at said entry position, rotating said received vessel to said read position, and not accepting any other vessels at said entry position while a received vessel is in said read station;

wherein said read station is capable of rotating a transferred vessel from said entry position to said read position independently of motion of said plurality of vessels through said defined recirculating path, to thereby allow different vessels to remain on said defined recirculating path for different amounts of time.

EVIDENCE APPENDIX:

None.

RELATED PROCEEDINGS AAPPENDIX:

None.